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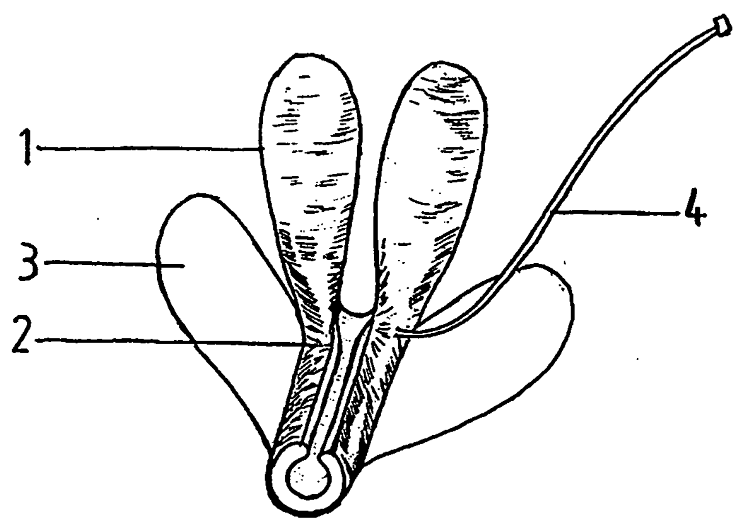
(54) Title: DEVICE FOR GENUINE STRESS INCONTINENCE IN THE FEMALE



(57) Abstract

This implantable continence device consists of a hydraulic and a mechanical component. The hydraulic component comprises two retropubic subperitoneal fluid filled balloon reservoirs (1) which communicates with a periurethral cuff (2) to form a complete hydraulic system. At the upper end of the periurethral cuff (2) there is a fluid outlet channel (4) to regulate the biocompatible fluid in the hydraulic system. The mechanical component comprises of two strips of biocompatible mesh extending sideways from the base of the periurethral cuff (2) to form two wings (3). Both wings are transfixed to pelvic fascia and white line of the pelvis using non absorbable material. The base of the periurethral cuff (2) and the necks of the balloon reservoirs are reinforced to achieve non kink properties. Both components are made of suitable biocompatible material and the hydraulic system is filled with biocompatible fluid. This device improves both resting and stress urethral pressure profile and prevents herniation of bladder neck and proximal urethra during the periods of increased intra-abdominal pressure.

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DEVICE FOR GENUINE STRESS INCONTINENCE IN THE FEMALE

This device relates to an implant for the treatment of genuine stress urinary incontinence in the female.

Stress incontinence is urine loss that occurs when sudden increase in intra-abdominal pressure force urine past the urethral sphincter mechanism. This usually occurs during conditions of physical activity which stress the bladder outlet to such a degree that it can no longer remain closed, resulting a momentary urine loss. This is a common and distressing condition.

The two major factors responsible for stress incontinence are loss of support of the proximal urethra and bladder neck which produces hypermobility of these structures and results in stress incontinence due to bladder neck displacement during physically stressful conditions and intrinsic sphincter weakness which may lead to stress incontinence. These factors usually coexist in the same patient.

At present various surgical procedures are being carried out for the treatment of genuine stress incontinence in the female. The objectives of surgery are to restore the pelvic floor so that hypermobility of the bladder neck during stress is minimized and to cause some degree of outflow resistance in the urethra. The results of the surgical procedures are good. However, the long term results are poor as restored pelvic floor 'falls' back to previous state due to plastic properties of pelvic fascia and paraurethral tissues.

This implantable continence device consists of a hydraulic and a mechanical component. The hydraulic component comprises of two retropubic subperitoneal fluid filled balloon reservoirs 1 which communicates with a periurethral cuff 2 to form a complete hydraulic system. At the upper end of the periurethral cuff 2 there is a fluid outlet channel 4 to regulate the biocompatible fluid in the hydraulic system. The mechanical component comprises of two strips of biocompatible mesh extending sideways from the base of the periurethral cuff 2 to form two wings 3. Both wings are transfixed to pelvic fascia and white line of the pelvis

using non absorbable material. The base of the periurethral cuff 2 and the necks of the balloon reservoirs are reinforced to achieve non kink properties. Both components are made of suitable biocompatible material and the hydraulic system is filled with biocompatible fluid.

The design of the device is further described with reference to the accompanying drawings.

Figure 1	Shows the basic components of the device.
Figure 2	Shows the basic components seen from Right side.
Figure 3	Shows a cross section of the device at the proximal end of the device.
Figure 4	Shows a sagittal section of the female pelvis with the device in situ.

When properly implanted both balloon reservoirs 1 occupy the retropubic space and extends subperitonealy beyond the upper margin of the symphysis pubis. The periurethral cuff 2 surrounds the posterior and lateral aspects of the bladder neck and proximal urethra. The wings 3 are transfixed to the endopelvic fascia and to the white line of the pelvis to form a platform. The fluid outlet channel 4 is buried subcutaneously in the suprapubic area. The activation of the device could be done later by inserting biocompatible fluid via the fluid outlet channel 4.

During the periods of stress, increased intra-abdominal pressure is directly transmitted to the balloon reservoirs 1 which transmits the pressure to the bladder neck and the proximal urethra via the hydraulic system to periurethral cuff 2 resulting in improved stress urethral pressure profile.

During the periods of stress, there is reflex contraction of the pelvic floor which transmits the contraction force along the wings 3 causing a resultant upward counterforce that prevents herniation of the bladder neck and proximal urethra.

The resting urethral pressure could also be increased to the required levels by adjusting the pressure in the hydraulic system, especially for patients who have higher grades of stress incontinence due to intrinsic sphinteric weakness.

The periurethral cuff 2 could be lengthened to cover distal parts of the urethra so that increased intra-abdominal pressure is transmitted to more distal parts of the urethra. This would act as a second line of defence to prevent the escape of any urine which happens to enter the urethra. In addition the elevation of the urethra and bladder neck could be achieved by increasing the outer diameter of the periurethral cuff 2.

Thus, this device influences all the known mechanisms of continence by enhancing the transmission of increased intra-abdominal pressure to bladder neck and proximal urethra during stress, prevention of herniation of posterior urethra and bladder neck, and improving the resting urethral pressure. Summation of these mechanisms could ultimately increase the patient's margin for incontinence and push her above the threshold for urinary leakage. The contribution from each component of the device to gain continence could be determined by prior urodynamic investigations. The fluid pressure of the hydraulic system could be re-adjusted periodically to maintain the optimal resting urethral pressure. The implant could be used as a primary treatment or as a secondary procedure following unsuccessful primary surgery.

CLAIMS

1. An implantable incontinence device for genuine stress incontinence in the female comprising a hydraulic component and mechanical component, the former having two subperitoneal fluid filled balloon reservoirs 1 which directly communicates with a periurethral cuff 2, means for transmission of increased intra-abdominal pressure to the bladder neck and proximal urethra, and the said mechanical component having two strips of biocompatible mesh forming two wings 3 extending sideways from the base of the periurethral cuff 2 which are transfixed to pelvic fascia means for prevention of hypermobility of the bladder neck and proximal urethra during the periods of increased intra-abdominal pressure.

2. The hydraulic component of the incontinence device as claimed in claim 1 facilitates the transmission of increased intra-abdominal pressure to the bladder neck and proximal urethra resulting in improved stress urethral pressure profile.

3. The fluid pressure in the hydraulic component claimed in claim 1 could be adjusted by regulating the fluid pressure via the fluid channel 4 to have the optimal resting urethral pressure profile.

4. The outer diameter of the periurethral cuff 2 claimed in claim 1 could be increased to improve elevation of the bladder neck and the proximal urethra.

5. The mechanical component of the incontinence device claimed in claim 1 comprises of two strips of biocompatible mesh 3 extending sideways from the base of the periurethral cuff 2 which are transfixed to pelvic fascia transmits the upward counterforce produced by pelvic floor muscles to the base of the periurethral cuff 2, thus preventing herniation of proximal urethra and bladder neck during the periods of increased intra-abdominal pressure.

6. The subperitoneal fluid filled reservoirs 1, periurethral cuff 2 and wings 3 mentioned in claim 1 could be made in various sizes to suit individual urological requirements.

7. An implantable incontinence device for genuine stress incontinence as herein described and illustrated in the accompanying drawings 1 - 4.

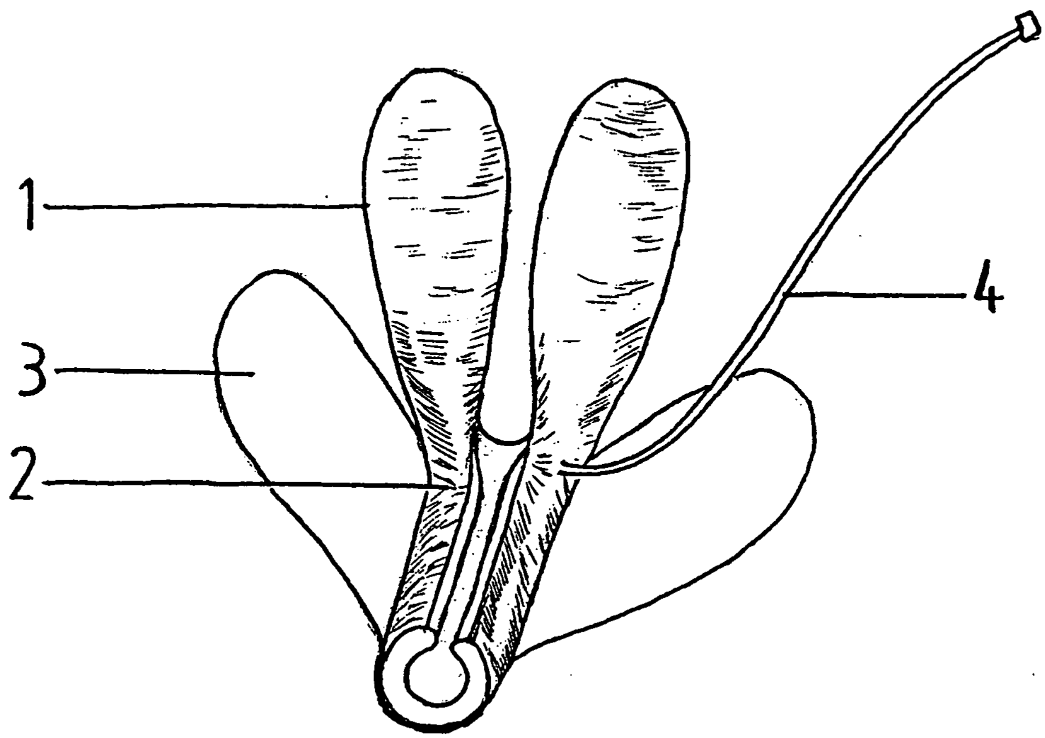

Fig1

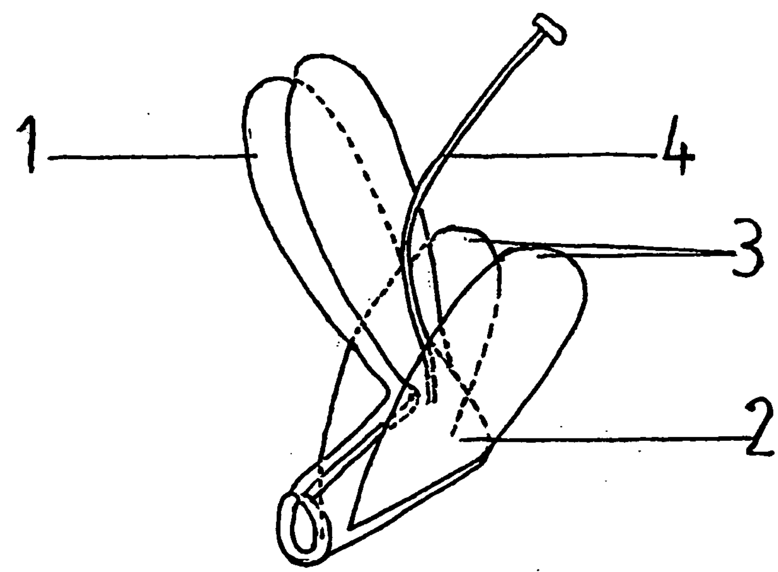

Fig 2

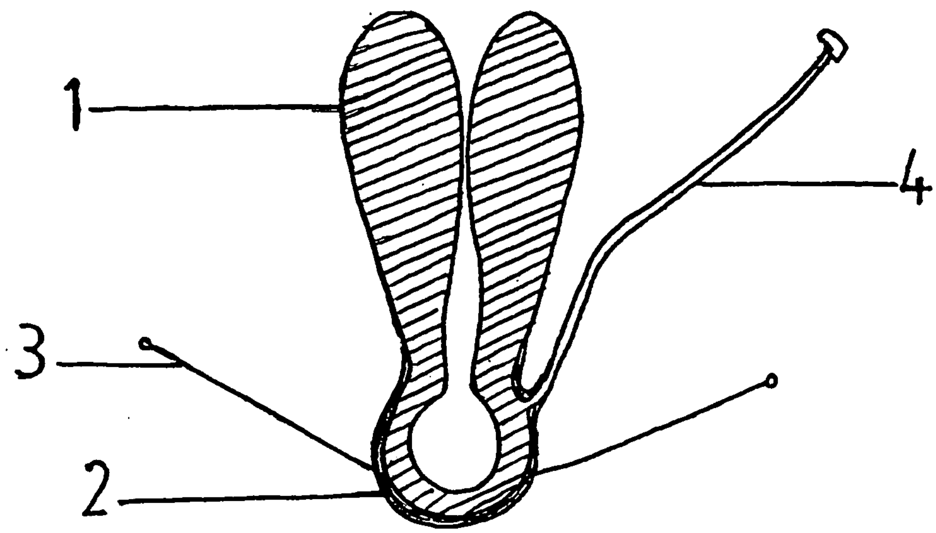

Fig 3

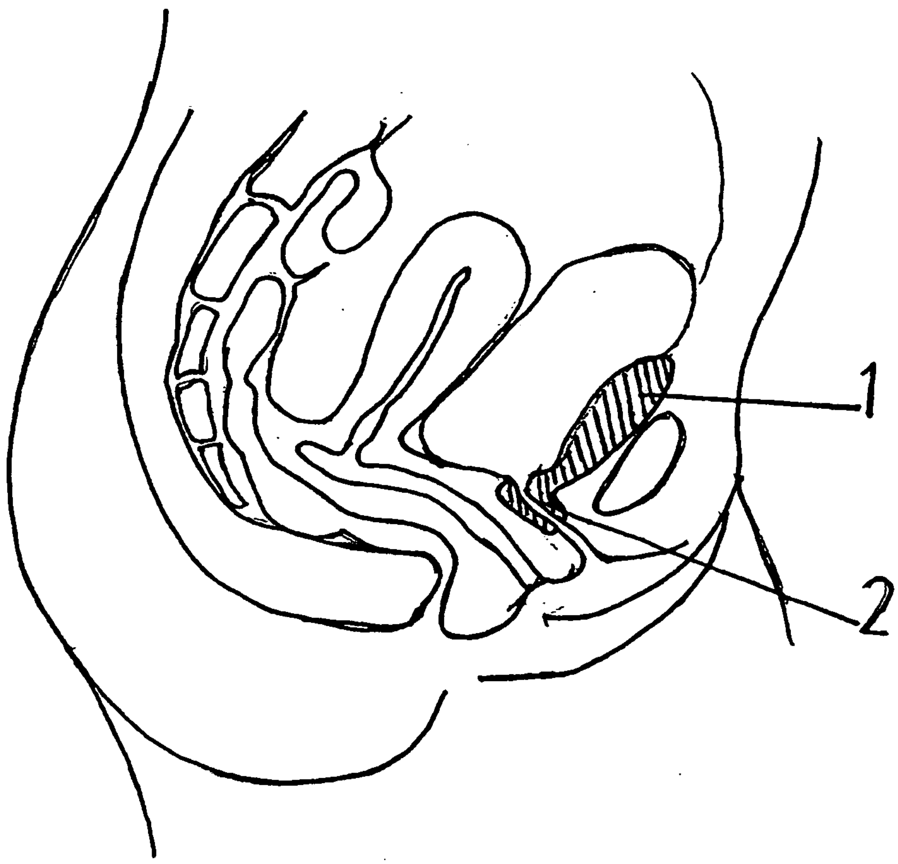

Fig 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 97/00670

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 639 355 A (RULL JOHANN DR MED) 22 February 1995 see the whole document ---	1,3-6
Y	EP 0 207 426 A (HABLEY MEDICAL TECHNOLOGY CORP) 7 January 1987 see abstract; figure 1 ---	1,3-6
A	US 4 969 474 A (SCHWARZ GERALD R) 13 November 1990 ---	
A	WO 88 00064 A (HABLEY MEDICAL TECHNOLOGY CORP) 14 January 1988 ---	
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Date of the actual completion of the international search	Date of mailing of the international search report
17 September 1997	29.10.97

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna. .l Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0639355 A	22-02-95	DE 4328158 A	23-02-95
EP 0207426 A	07-01-87	US 4634443 A	06-01-87
		AU 5977886 A	08-01-87
		CA 1253651 A	09-05-89
		IN 165850 A	27-01-90
		JP 1964176 C	25-08-95
		JP 6091890 B	16-11-94
		JP 62008752 A	16-01-87
US 4969474 A	13-11-90	CA 2092925 A	19-04-92
		EP 0553075 A	04-08-93
		WO 9206652 A	30-04-92
		US 5012822 A	07-05-91
		US 5097848 A	24-03-92
		US 5123428 A	23-06-92
WO 8800064 A	14-01-88	US 4773393 A	27-09-88
		AU 603130 B	08-11-90
		AU 7750987 A	29-01-88
		DE 3781786 A	22-10-92
		EP 0274517 A	20-07-88
		JP 63024940 A	02-02-88
US 3789828 A	05-02-74	NONE	